K100226

# 1.4 510(K) SUMMARY

## 510(K) SUMMARY

MAR 1 8 2010

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: 100226

**Manufacturer:**

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15F, No 868-2, Jhongjheng Road, Jhonghe City
Taipei County, 235, Taiwan

**Official Correspondent:**

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**Date of Submission:**

January 25, 2010

**Classification name:**

Clinical Electronic Thermometer / Class II

**Proprietary Name:**

Wireless Body Temperature Monitor/ BTM-D1X series (BTM-D1C, D, E, F, G & H)

**Common name:**

Wireless Body Temperature Monitor

**Regulatory Reference:**

21 CFR 880.2910

**Predicate Device:**

Rio Flexon Technology Co., Ltd
Wireless Body Temperature Monitor, BTM-D1X series (K081256)

**Intended Use:**

The Wireless Body Temperature Monitor, model BTM-D1X series (model BTM-D1C, D, E, F, G and H), is a battery-operated electronic device with intended use of measuring human ear temperature precisely and continuously monitoring armpit temperature via wireless signal transmission of the measuring result. This device is reusable and is intended for ear temperature measurement as well as armpit temperature monitoring for persons over two years old. Model BTM-D1C has two functions, both ear temperature measurement and armpit temperature monitoring. The rest of models, BTM-D1D, E, F, G and H, have only the function of armpit temperature monitoring.

**Device Description:**

The Wireless Body Temperature Monitor BTM-D1X series includes models BTM-D1C, D, E, F, G and H. This device is a battery-operated electronic device that is intended to be worn at left arm to monitor the armpit temperature continuously. In addition, BTM-D1C has the additional function of an ear thermometer.

The device is composed of two operational parts, the receiver and armband. An optional accessory may be included to assist in affixing the sensor of the armband more tightly. The receiver is the main operation unit on which the ear thermometer, the measuring circuit, LCD display control circuit, and the main operation keys are included. The armband was designed and constructed with a thermo sensor and signal communication unit. For the monitoring operation, both the receiver and armband must be switched on. Soon after these two parts are switched on, the wireless signal communication will set up between the receiver and the armband. The temperature monitoring signal measured at armpit will be continuously indicated on the LCD of the receiver and will update every 12 seconds.

The device also has a high/low audible alarm, which will sound if the body temperature goes above the high alarm temperature or below the low alarm temperature set by the user.

In addition to the continuous armpit temperature monitoring, the user can also operate the functional key on the receiver to take an ear temperature measurement at any time if needed. The reading on the LCD screen will return to the armpit temperature after 30 seconds.

This system uses a 3.0V DC battery for operation of the complete system. Whenever the battery is low, the MCU circuit will detect the low battery condition automatically, and will display "Low battery" on the LCD display. The BTM-D1X series was designed and verified according to the US standard ASTM E1112-00 and ASTM E1965-02.

**Comparison to Predicate Devices:**

The new BTM-D1X series is the same as the predicate BTM-D1X series under K081256, except for the addition of the high/low alarm function.

| Element of comparison | Prior BTM-D1C model from K081256 | Prior BTM-D1D/E/F/G/H models from K081256 | Modified BTM-D1C model | Modified BTM-D1D/E/F/G/H models |
|---|---|---|---|---|
| Ear Thermometer type | Infrared tympanic thermometer | N/A | Infrared tympanic thermometer | N/A |
| Intended use | Intended use of measuring human ear temperature precisely and continuously monitoring armpit temperature via wireless signal transmission of the measuring result. This device is reusable and intended for ear temperature measurement as well as armpit temperature monitoring for persons over two years old | This device is intended to continuously monitor armpit temperature via wireless signal transmission of measuring result. The device is intended to be used for persons over two years old. | Intended use of measuring human ear temperature precisely and continuously monitoring armpit temperature via wireless signal transmission of the measuring result. This device is reusable and intended for ear temperature measurement as well as armpit temperature monitoring for persons over two years old | This device is intended to continuously monitor armpit temperature via wireless signal transmission of measuring result. The device is intended to be used for persons over two years old. |
| Brand Name | Rio Flexon | Rio Flexon | Rio Flexon | Rio Flexon |
| Signal processing and display | Wireless 2.4G transmission & display on LCD screen of monitor | Wireless 2.4G transmission & display on LCD screen of monitor | Wireless 2.4G transmission & display on LCD screen of monitor | Wireless 2.4G transmission & display on LCD screen of monitor |
| Power requirements of Armband | 3V / CR2032 Lithium | 3V / CR2032 Lithium | 3V / CR2032 Lithium | 3V / CR2032 Lithium |
| Power requirement of Receiver | AAA battery x 2pcs | AAA battery x 2pcs | AAA battery x 2pcs | AAA battery x 2pcs |
| Temperature range | 25 °C - 43 °C | 25 °C - 43 °C | 25 °C - 43 °C | 25 °C - 43 °C |
| High/low alarm setting | N/A | N/A | Manual | Manual |

| Element of comparison | Prior BTM-D1C model from K081256 | Prior BTM-D1D/E/F/G/H models from K081256 | Modified BTM-D1C model | Modified BTM-D1D/E/F/G/H models |
|---|---|---|---|---|
| High alarm temperature range | N/A | N/A | 36°C - 40°C | 36°C - 40°C |
| Low alarm temperature range | N/A | N/A | 32°C - 35.5°C | 32°C - 35.5°C |
| Ambient temperature | 15 °C - 42 °C (with 95% RH humidity) | 15 °C - 42 °C (with 95% RH humidity) | 15 °C - 42 °C (with 95% RH humidity) | 15 °C - 42 °C (with 95% RH humidity) |
| Storage condition | -20 °C - 50 °C (with 95% RH humidity) | -20 °C - 50 °C (with 95% RH humidity) | -20 °C - 50 °C (with 95% RH humidity) | -20 °C - 50 °C (with 95% RH humidity) |
| Accuracy for armpit temperature | ± 0.1 °C | ± 0.1 °C | ± 0.1 °C | ± 0.1 °C |
| Accuracy for ear temperature | ± 0.2 °C for 36 °C - 39 °C; ± 0.3 °C for the others | N/A | ± 0.2 °C for 36 °C - 39 °C; ± 0.3 °C for the others | N/A |
| Monitoring time | 24 hours | 24 hours | 24 hours | 24 hours |
| Components | 1. Receiver IC#: HT-49R50<br>2. Armband IC#: HT-46R52<br>3. Ear temperature measuring module<br>4. RF transmission module (2.4GHz) | 1. Receiver IC#: HT-49R50<br>2. Armband IC#: HT-46R52<br>3. RF transmission module (2.4GHz) | 1. Receiver IC#: HT-49R50<br>2. Armband IC#: HT-46R52<br>3. Ear temperature measuring module (for BTM-D1C models only)<br>4. RF transmission module (2.4GHz) | 1. Receiver IC#: HT-49R50<br>2. Armband IC#: HT-46R52<br>3. RF transmission module (2.4GHz) |
| Sensor | SENTECH sensor | SENTECH sensor | SENTECH sensor | SENTECH sensor |
| Electrical safety standard | EN 60601-1 | EN 60601-1 | EN 60601-1 | EN 60601-1 |
| EMC conformity | EN 60601-1-2 & FCC | EN 60601-1-2 & FCC | EN 60601-1-2 & FCC | EN 60601-1-2 & FCC |
| Conformity of | ISO 10993 | ISO 10993 | ISO 10993 | ISO 10993 |

| Element of comparison | Prior BTM-D1C model from K081256 | Prior BTM-D1D/E/F/G/H models from K081256 | Modified BTM-D1C model | Modified BTM-D1D/E/F/G/H models |
|---|---|---|---|---|
| Bio-compatibility for the skin contact material (Armband) | **Cytotoxicity /** Negative **Sensitization /** Negative **Primary skin irritation /** Negative | **Cytotoxicity /** Negative **Sensitization /** Negative **Primary skin irritation /** Negative | **Cytotoxicity /** Negative **Sensitization /** Negative **Primary skin irritation /** Negative | **Cytotoxicity /** Negative **Sensitization /** Negative **Primary skin irritation /** Negative |
| Measuring location | Armpit and ear (for BTM-D1C models only) | Armpit and ear (for BTM-D1C models only) | Armpit and ear (for BTM-D1C models only) | Armpit and ear (for BTM-D1C models only) |

**Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence**

Compliance to applicable voluntary standards includes ASTM E1112:2000, ASTM E1965:2002, EN 60601-1, and EN 60601-1-2. All of the required conformity reports are included in the 510(k) submission documents.

**Discussion of clinical report for measurement accuracy**

The ear temperature measuring function of the modified BTM-D1X series (BTM-D1C model only) is the same as the predicate BTM-D1X series (BTM-D1C model only) from K081256, which involved the integration of the 510(k) cleared model, Taidoc/TD-1107 (K050463). Therefore, the clinical report for measurement accuracy (per ASTM E1965:2002), which was included in the 510(k) submission for Taidoc/TD-1107 (K050463) and referenced in K081256, is still applicable for the modified BTM-D1X series.

No additional clinical report is included in this 510(k) submission.

**Performance Tests:**

| Test Performed | Laboratory |
|---|---|
| 1. EN 60601-1 | Electronics Testing Center, Taiwan |
| 2. EN 60601-1-2/ EN 300 440-2 / EN 3011489-1/-3 | Electronics Testing Center, Taiwan |
| 3. ASTM/ E 1112-00 | Rio Flexon Technology Co., Ltd |
| 4. ASTM/ E 1965-02 | Taidoc Technology Corporation |
| 5. Biocompatibility (ISO 10993) | Taiwan National Chung-Hsing University Lab |
| 6. FCC | Electronics Testing Center, Taiwan |

**Conclusions:**

The modified device has the same fundamental scientific technology and intended use as the predicate device. The only difference between the modified BTM-D1X series and the predicate device (K081256/BTM-D1X series) is the addition of the high/low alarm function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 1 8 2010

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Jhonghe City, Taipei County
China (TAIWAN) 235

Re: K100226
Trade/Device Name: Wireless Body Temperature Monitor/Model: BTM-D1C,D,E,F,G and H.
Regulation Number: 21CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: March 4, 2010
Received: March 5, 2010

Dear Mr. Liao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

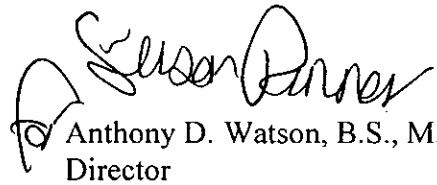
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
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Radiological Health

Enclosure

# Indications for Use

510(k) Number:

Device Name: Wireless Body Temperature Monitor / Model: BTM-D1C, D, E, F, G and H.

Indication for Use:

The Wireless Body Temperature Monitor, model BTM-D1X series (model BTM-D1C, D, E, F, G and H), is a battery-operated electronic device with intended use of measuring human ear temperature precisely and continuously monitoring armpit temperature via wireless signal transmission of the measuring result. This device is reusable and is intended for ear temperature measurement as well as armpit temperature monitoring for persons over two years old. Model BTM-D1C has two functions, both ear temperature measurement and armpit temperature monitoring. The rest of models, BTM-D1D, E, F, G and H, have only the function of armpit temperature monitoring.

Prescription Use _____ AND/OR Over-The-Counter Use __X__

(Part 21 CFR 801 Subpart D) (21CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices



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